PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	GIL M. VARDI et al.	Confirmation No.:	3207
Serial No.:	10/762,562	Examiner:	THOMAS SWEET
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Docket No.:	1001.2273105	Customer No.:	28075
Title:	CATHETER WITH ATTACHED FLEXIBLE SIDE SHEATH		

APPEAL BRIEF

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PO Box 1450
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Lynn Thompson 3-10-09
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Pursuant to 37 C.F.R. § 41.37, Appellants hereby submit this Appeal Brief in furtherance of the Notice of Appeal filed on October 10, 2008 and of the Notice of Panel Decision from Pre-Appeal Review dated February 10, 2009. Appellants authorize the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of $540.00 to be charged to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

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I. REAL PARTY IN INTEREST

The real party in interest in this appeal is Boston Scientific Scimed, Inc., a corporation organized and existing under the laws of the State of Minnesota, and having its principal offices at One Scimed Place Maple Grove, MN 55311. An assignment from co-inventors Gil M. Vardi, Charles J. Davidson, and Eric Williams conveying all right, title and interest in the invention to Advanced Stent Technologies, Inc., a subsidiary of Boston Scientific Scimed, Inc., has been recorded at Reel 010625, Frame 0071.

II. RELATED APPEALS AND INTERFERENCES

There are no other known appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 8 and 10-23 have been canceled without prejudice by prior Amendment and claims 1-7, 9, and 24 remain pending in the application. Claims 1-7, 9, and 24 stand finally rejected under 35 U.S.C. § 103(a) over Wilson et al. (U.S. Patent No. 6,165,195) in view of Fischell et al. (U.S. Patent No. 5,749,825). Appellant hereby appeals the final rejection of all pending claims, namely claims 1-7, 9, and 24.

IV. STATUS OF AMENDMENTS

Appellant received a Final Office Action mailed July 1, 2008. No Amendment After Final was filed and no Advisory Action was received. A Notice of Appeal and Pre-Appeal Brief Request for Review were filed by Appellant on October 31, 2008. A Notice of Panel Decision

from Pre-Appeal Brief Request was mailed on February 10, 2009 maintaining the rejections of the claims and resetting the time period for filing an Appeal Brief. All pending claims, namely claims 1-7, 9, and 24, are being appealed.

V. SUMMARY OF CLAIMED SUBJECT MATTER [1]

The present invention relates generally to methods for delivery a stent to a vessel bifurcation with a catheter system. Independent claim 1 recites a method of positioning a main stent (see, for example, specification page 7, lines 2-8; reference numeral 25 in Figures 2A-B and 4-10) in a main vessel at a vessel bifurcation such that a side opening (see, for example, specification page 7, lines 4-8; reference numeral 27 in Figures 2A-B and 4-10) in the main stent is positioned at an ostium of a branch vessel (see, for example, specification page 7, lines 6-8). The method comprises: positioning a main guidewire (see, for example, specification page 7, lines 1-2 and 9-10; reference numeral 21 of Figures 3-7) in the main vessel such that a distal end (see, for example, specification page 7, lines 9-10; reference numeral 22 of Figures 3-7) of the main guidewire extends past the vessel bifurcation (see, for example, specification page 7, lines 9-10); advancing a stent delivery system (see, for example, specification page 7, lines 1-2 and 9-10; reference numeral 21 of Figures 3-7) over the main guidewire to a position proximate the bifurcation (see, for example, specification page 6, line 31 through page 7, line 5; reference numeral 10 of Figures 1, 4, and 5), the stent delivery system comprising a catheter (see, for example, specification page 6, line 31 through page 7, line 5; reference numeral 12 of Figures 1-2 and 4-7) with a flexible side sheath attached thereto (see, for example, specification page 6, line 31 through page 7, line 5; reference numeral 14 of Figures 1-2 and 4-7), wherein the catheter

[1] The references to the specification and drawings provided herein are exemplary, and are not deemed to be limiting.

is received over the main guidewire (see, for example, specification page 6, line 34 through page 7, line 1 and page 7, lines 11-12; Figure 4), and wherein the main stent is positioned over the catheter with the flexible side sheath positioned to pass through an interior of the main stent and out the side opening in the main stent (see, for example, specification page 7, lines 2-5 and 12-15; Figure 4), the flexible side sheath having a distal end portion extending distal of the side opening of the stent (see, for example, specification page 7, lines 3-5 and 12-16); subsequently, advancing a branch guidewire (see, for example, specification page 7, lines 1-2 and 16-22; reference numeral 31 of Figures 5-8 and 10) through the flexible side sheath attached to the catheter and into the branch vessel (see, for example, specification page 7, lines 15-16; Figure 5); subsequently, advancing the catheter over the main guidewire while advancing the flexible side sheath over the branch guidewire, wherein the distal end portion of the flexible side sheath advances into the branch vessel (see, for example, page 7, lines 23-27; Figure 6A and 6B); and viewing relative movement of a marker (see, for example, specification page 8, lines 4-22; reference numeral 55 of Figures 2A and 6A-B) positioned on the distal end portion of the flexible side sheath with respect to at least one marker (see, for example, specification page 7, line 33 through page 8, line 22; reference numerals 50, 51, 52 of Figures 2A and 6A-B) positioned on the catheter when advancing the flexible side sheath over the branch guidewire, wherein the relative movement indicates that the distal end portion of the flexible side sheath is advancing into the ostium of the branch vessel, thereby indicating a relative position of the side opening of the main stent with respect to the ostium of the branch vessel (see, for example, page 7, lines 27-32 and page 8, lines 6-12).

Claim 2, which is dependent from claim 1, further recites wherein viewing the relative movement of the marker positioned on the flexible side sheath with respect to the at least one

marker positioned on the catheter comprises: viewing an increasing separation distance between the marker positioned on the flexible side sheath with respect to the at least one marker positioned on the catheter as the catheter is advanced over the main guidewire while the flexible side sheath is simultaneously advanced over the branch guidewire (see, for example, specification page 8, lines 6-12).

Claim 3, which is dependent from claim 1, further recites wherein, viewing the at least one marker positioned on the catheter comprises viewing markers positioned adjacent the distal and proximal ends of the main stent (see, for example, specification page 7, line 33 through page 8, line 5; page 8, lines 17-22).

Independent claim 7 recites a method of positioning a main stent (see, for example, specification page 7, lines 2-8; reference numeral 25 in Figures 2A-B and 4-10) at a vessel bifurcation between a main vessel and a branch vessel such that a side opening (see, for example, specification page 7, lines 4-8; reference numeral 27 in Figures 2A-B and 4-10) in the main stent is positioned at an ostium of the branch vessel (see, for example, specification page 7, lines 6-8). The method comprises: positioning a main guidewire (see, for example, specification page 7, lines 1-2 and 9-10; reference numeral 21 of Figures 3-7) in the main vessel such that a distal end (see, for example, specification page 7, lines 9-10; reference numeral 22 of Figures 3-7) of the main guidewire extends past the bifurcation (see, for example, specification page 7, lines 9-10); advancing a stent delivery system (see, for example, specification page 7, lines 1-2 and 9-10; reference numeral 21 of Figures 3-7) over the main guidewire to a position proximate the bifurcation (see, for example, specification page 6, line 31 through page 7, line 5; reference numeral 10 of Figures 1, 4, and 5), the stent delivery system comprising a catheter (see, for example, specification page 6, line 31 through page 7, line 5; reference numeral 12 of Figures 1-

2 and 4-7) with a flexible side sheath attached thereto (see, for example, specification page 6, line 31 through page 7, line 5; reference numeral 14 of Figures 1-2 and 4-7), wherein the catheter is received over the main guidewire (see, for example, specification page 6, line 34 through page 7, line 1 and page 7, lines 11-12; Figure 4), and wherein the main stent is positioned over the catheter with the flexible side sheath positioned to pass through the interior of the main stent and out the side opening in the main stent (see, for example, specification page 7, lines 2-5 and 12-15; Figure 4), the flexible side sheath having a distal end portion extending distal of the side opening of the stent (see, for example, specification page 7, lines 3-5 and 12-16); subsequently, advancing a branch guidewire (see, for example, specification page 7, lines 1-2 and 16-22; reference numeral 31 of Figures 5-8 and 10) through the flexible side sheath and into the branch vessel (see, for example, specification page 7, lines 15-16; Figure 5); and subsequently, advancing the catheter over the main guidewire while advancing the flexible side sheath over the branch guidewire, wherein the distal end portion of the flexible side sheath advances into the branch vessel such that the side opening in the main stent is positioned at the ostium of the branch vessel (see, for example, page 7, lines 23-27; Figure 6A and 6B).

Claim 9, which is dependent from claim 7, recites further comprising: viewing relative movement of a marker (see, for example, specification page 8, lines 4-22; reference numeral 55 of Figures 2A and 6A-B) positioned on the flexible side sheath with respect to at least one marker (see, for example, specification page 7, line 33 through page 8, line 22; reference numerals 50, 51, 52 of Figures 2A and 6A-B) positioned on the catheter, wherein the relative movement indicates that the distal end portion of the flexible side sheath is advancing into the ostium of the branch vessel, thereby indicating a relative position of the side opening of the main stent with

respect to the ostium of the branch vessel (see, for example, page 7, lines 27-32 and page 8, lines 6-12).

VI. GROUNDS OF REJECTIONS TO BE REVIEWED ON APPEAL

1. Whether claims 1-7, 9, and 24 are unpatentable under 35 U.S.C. § 103(a) over Wilson et al. (U.S. Patent No. 6,165,195) in view of Fischell et al. (U.S. Patent No. 5,749,825)?

VII. ARGUMENT

A. Claims 1-7, 9, and 24 are patentable over Wilson et al. (U.S. Patent No. 6,165,195) in view of Fischell et al. (U.S. Patent No. 5,749,825) under 35 U.S.C. § 103(a).

1. Claims 1, 4, 5, 6, and 24 are patentable over Wilson et al. in view of Fischell et al.

On page 2 of the Final Office Action, claims 1-7, 9, and 24 were finally rejected by the Examiner under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (U.S. Patent No. 6,165,195) in view of Fischell et al. (U.S. Patent No. 5,749,825). It is axiomatic that "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (M.P.E.P. § 2143.03).

Turning to Independent claim 1, which recites:

> 1. A method of positioning a main stent in a main vessel at a vessel bifurcation such that a side opening in the main stent is positioned at an ostium of a branch vessel, the method comprising:
>
> positioning a main guidewire in the main vessel such that a distal end of the main guidewire extends past the vessel bifurcation;
>
> advancing a stent delivery system over the main guidewire to a position proximate the bifurcation, the stent delivery system comprising a catheter with a flexible side sheath attached thereto, wherein the catheter is received over the main guidewire, and wherein the main stent is positioned over the catheter with the flexible side sheath positioned to pass through an interior of the main stent and out the side opening in the main stent, the flexible side sheath having a distal end

portion extending distal of the side opening of the stent;

subsequently, advancing a branch guidewire through the flexible side sheath attached to the catheter and into the branch vessel;

subsequently, advancing the catheter over the main guidewire while advancing the flexible side sheath over the branch guidewire, wherein the distal end portion of the flexible side sheath advances into the branch vessel; and

viewing relative movement of a marker positioned on the distal end portion of the flexible side sheath with respect to at least one marker positioned on the catheter when advancing the flexible side sheath over the branch guidewire, wherein the relative movement indicates that the distal end portion of the flexible side sheath is advancing into the ostium of the branch vessel, thereby indicating a relative position of the side opening of the main stent with respect to the ostium of the branch vessel.

Nowhere does Wilson et al. or Fischell et al., either alone or in combination, appear to teach or suggest "viewing relative movement of a maker positioned on the distal end portion of the flexible side sheath with respect to at least one marker positioned on the catheter when advancing the flexible side sheath over the branch guidewire, wherein the relative movement indicates that the distal end portion of the flexible side sheath is advancing into the ostium of the branch vessel, thereby indicating a relative position of the side opening of the main stent with respect to the ostium of the branch vessel", as recited in claim 1.

Wilson et al. appears to teach a main-vessel catheter assembly 50 for implanting a main-vessel stent 20 into a main-vessel 6 and a side-branch catheter assembly 30 for implanting an angled stent 10 into a side-branch vessel 5. With regards to the use of markers to assist in alignment of the main-vessel catheter assembly 50 or the side-branch catheter assembly 30, Wilson et al. at column 17, line 64 through column 18, line 14, recites:

> In order to assist in properly aligning both proximal angled stent 10 and main-vessel stent 20 in side-branch vessel 5 and main-vessel 6, respectively, positioning guide wire lumen 39A, on side-branch catheter 31, and guide wire lumen 55A, on main-vessel catheter 50, can be radiopaque, or have a radiopaque marker associated therewith so that they are visible under fluoroscopy. Thus, when advancing side-branch catheter 31 and main-vessel catheter 50, the proper orientation can be more easily determined by viewing the position of positioning

> guide wire lumen 39A in connection with main-vessel 6 or positioning guide wire lumen 55A in connection with aligning aperture 25 with side-branch vessel 5. Additionally, positioning guide wire 56A for positioning main-vessel stent 20 and positioning guide wire 41A for positioning angled stent 10 are either radiopaque or have radiopaque portions, such as gold markers, to assist in positioning and orienting the catheters and stents during implantation and deployment.

(Emphasis added). As can be clearly seen, this passage appears to merely teach providing a radiopaque marker on the guidewire lumen 55A of the main-vessel catheter 50 or providing a radiopaque marker on guidewire lumen 39A for a side-branch catheter 30. In either case, the passage appears to teach using a radiopaque marker on a single lumen of the respective catheter to determine the proper orientation and alignment of the catheter with the side-branch vessel 5. The passage also appears to teach that the positioning guidewires 41A or 56A may be either radiopaque or have radiopaque portions, such as gold markers, to assist in positioning and orienting the catheters and stents during implantation and deployment. However, nowhere does this passage or any other passage of Wilson et al. appear to teach or suggest using radiopaque marker(s) on both the main guidewire lumen and the secondary guidewire lumen of the catheter.

Further, with a configuration having a radiopaque marker as disclosed by Wilson et al., or even multiple radiopaque markers but on a single lumen, Appellant must respectfully assert that there would appear to be no relative movement between the marker(s). As such, nothing in the teachings of Wilson et al. appears to teach or suggest "viewing relative movement of a maker positioned on the distal end portion of the flexible side sheath with respect to at least one marker positioned on the catheter when advancing the flexible side sheath over the branch guidewire, wherein the relative movement indicates that the distal end portion of the flexible side sheath is advancing into the ostium of the branch vessel, thereby indicating a relative position of the side opening of the main stent with respect to the ostium of the branch vessel", as recited in claim 1.

In the Final Office Action, the Examiner relied on column 17, line 64 through column 18, line 14 as teaching or suggesting "viewing relative movement of a maker positioned on the distal end portion of the flexible side sheath with respect to at least one marker positioned on the catheter when advancing the flexible side sheath over the branch guidewire, wherein the relative movement indicates that the distal end portion of the flexible side sheath is advancing into the ostium of the branch vessel, thereby indicating a relative position of the side opening of the main stent with respect to the ostium of the branch vessel". However, as discussed above, nothing in this passage appears to teach or suggest such a limitation or even a device capable of such a limitation.

Furthermore, in the Final Office Action the Examiner appears to rely on the stent and wire of Wilson et al. as including the claimed markers. However, it is clear from claim 1 that the claimed relative movement is between a marker positioned on the distal end portion of the flexible side sheath and at least one marker positioned on the catheter. Further, claim 1 recites that the stent delivery system comprises a catheter with a flexible side sheath attached thereto, wherein the catheter is received over the main guidewire. Accordingly, Appellant respectfully asserts that the markers on the guidewire and stent of Wilson et al. do not teach or suggest "viewing relative movement of a maker positioned on the distal end portion of the flexible side sheath with respect to at least one marker positioned on the catheter when advancing the flexible side sheath over the branch guidewire", as recited in claim 1. Further, nothing in Fischell et al. appears to remedy this shortcoming of Wilson et al.

Furthermore, nowhere does the combination of Wilson et al. and Fischell et al. appear to teach or suggest "the flexible sheath having a distal end portion extending distal of the side opening of the stent", as recited in claim 1. In the Final Office Action, the Examiner

acknowledges that Wilson et al. fails to teach or suggest this limitation, but then relies on Fischell et al. as teaching such a limitation. Appellant respectfully asserts that modifying the catheter of Wilson et al. to include the flexible side sheath of Fischell et al. would still not arrive at the claimed invention.

Fischell et al. appears to teach a sheath having a proximal end that extends only a short distance proximal of the stent. In such a configuration, it does not appear that a branch guidewire could be advanced through the side sheath subsequent to the stent delivery system being advanced through the vessel. In fact, in such a configuration, it appears that the stent delivery system would need to be advanced over the branch guidewire prior to the stent delivery system being advanced through the vessel. Thus, modifying the device of Wilson et al. to include the side sheath of Fischell et al. does not appear to arrive at the claimed invention.

Therefore, for at least these reasons, claim 1 is believed to be patentable over Wilson et al. and Fischell et al. Thus, the rejection of claim 1 under 35 U.S.C. § 103(a) is improper and should be reversed. For similar reasons and others, claims 2-6 and 24, which depend from claim 1 and include additional limitations, are believed to be patentable over Wilson et al. in view of Fischell et al. Thus, the rejection of claims 2-6 and 24 under 35 U.S.C. § 103(a) is improper and should be reversed.

2. Claim 2 is patentable over Wilson et al. in view of Fischell et al.

Claim 2 recites:

> 2. The method of claim 1, wherein viewing the relative movement of the marker positioned on the flexible side sheath with respect to the at least one marker positioned on the catheter comprises: viewing an increasing separation distance between the marker positioned on the flexible side sheath with respect to the at least one marker positioned on the catheter as the catheter is advanced over

the main guidewire while the flexible side sheath is simultaneously advanced over the branch guidewire.

Nothing in Wilson et al. or Fischell et al. appears to teach or suggest "viewing an increasing separation distance between the marker positioned on the flexible side sheath with respect to the at least one marker positioned on the catheter as the catheter is advanced over the main guidewire while the flexible side sheath is simultaneously advanced over the branch guidewire", as recited in claim 2.

As indicated at column 17, line 64 through column 18, line 14, Wilson et al. appears to merely teach providing a radiopaque marker on the guidewire lumen 55A of the main-vessel catheter 50 or providing a radiopaque marker on guidewire lumen 39A for a side-branch catheter 30. In either case, the passage appears to teach using a radiopaque marker on a single lumen of the respective catheter to determine the proper orientation and alignment of the catheter with the side-branch vessel 5. The passage also appears to teach that the positioning guidewires 41A or 56A may be either radiopaque or have radiopaque portions, such as gold markers, to assist in positioning and orienting the catheters and stents during implantation and deployment. However, nowhere does this passage or any other passage of Wilson et al. appear to teach or suggest using radiopaque marker(s) on both the main guidewire lumen and the secondary guidewire lumen of the catheter. As such, nothing in Wilson et al. appears to teach or suggest "viewing an increasing separation distance between the marker positioned on the flexible side sheath with respect to the at least one marker positioned on the catheter", as recited in claim 2. Further, nothing in Fischell et al. appears to remedy this shortcoming of Wilson et al. Therefore, for at least these reasons, claim 2 is believed to be patentable over Wilson et al. in view of

Fischell et al. Thus, the rejection of claim 2 under 35 U.S.C. § 103(a) is improper and should be reversed.

3. Claim 3 is patentable over Wilson et al. in view of Fischell et al.

Claim 3 recites:

> 3. The method of claim 1, wherein, viewing the at least one marker positioned on the catheter comprises viewing markers positioned adjacent the distal and proximal ends of the main stent.

Nothing in Wilson et al. or Fischell et al. appears to teach or suggest" viewing the at least one marker positioned on the catheter comprises viewing markers positioned adjacent the distal and proximal ends of the main stent".

Instead, Wilson et al. appears to teach providing a radiopaque marker on the guidewire lumen 55A of the main-vessel catheter 50 or providing a radiopaque marker on guidewire lumen 39A for a side-branch catheter 30. (See column 17, line 64 through column 18, line 14 of Wilson et al.). Nothing in Wilson et al. appears to teach markers positioned adjacent the distal and proximal ends of the main stent. Further, nothing in Fischell et al. appears to remedy this shortcoming of Wilson et al. Therefore, for at least these reasons, claim 3 is believed to be patentable over Wilson et al. in view of Fischell et al. Thus, the rejection of claim 3 under 35 U.S.C. § 103(a) is improper and should be reversed.

4. Claim 7 is patentable over Wilson et al. in view of Fischell et al.

Claim 7 recites:

> 7. (Previously Presented) A method of positioning a main stent at a vessel bifurcation between a main vessel and a branch vessel such that a side

opening in the main stent is positioned at an ostium of the branch vessel, the method comprising:

positioning a main guidewire in the main vessel such that a distal end of the main guidewire extends past the bifurcation;

advancing a stent delivery system over the main guidewire to a position proximate the bifurcation, the stent delivery system comprising a catheter with a flexible side sheath attached thereto, wherein the catheter is received over the main guidewire, and wherein the main stent is positioned over the catheter with the flexible side sheath positioned to pass through the interior of the main stent and out the side opening in the main stent, the flexible side sheath having a distal end portion extending distal of the side opening of the stent;

subsequently, advancing a branch guidewire through the flexible side sheath and into the branch vessel; and

subsequently, advancing the catheter over the main guidewire while advancing the flexible side sheath over the branch guidewire, wherein the distal end portion of the flexible side sheath advances into the branch vessel such that the side opening in the main stent is positioned at the ostium of the branch vessel.

Nowhere does the combination of Wilson et al. and Fischell et al. appear to teach or suggest "the flexible sheath having a distal end portion extending distal of the side opening of the stent", as recited in claim 7. In the Final Office Action, the Examiner acknowledges that Wilson et al. fails to teach or suggest this limitation, but then relies on Fischell et al. as teaching such a limitation. Appellant respectfully asserts that modifying the catheter of Wilson et al. to include the flexible side sheath of Fischell et al. would still not arrive at the claimed invention.

Fischell et al. appears to teach a sheath having a proximal end that extends only a short distance proximal of the stent. In such a configuration, it does not appear that a branch guidewire could be advanced through the side sheath subsequent to the stent delivery system being advanced through the vessel. In fact, in such a configuration, it appears that the stent delivery system would need to be advanced over the branch guidewire prior to the stent delivery system being advanced through the vessel. Thus, modifying the device of Wilson et al. to include the side sheath of Fischell et al. does not appear to arrive at the claimed invention.

Therefore, for at least these reasons, claim 7 is believed to be patentable over Wilson et al. and Fischell et al. Thus, the rejection of claim 7 under 35 U.S.C. § 103(a) is improper and should be reversed. For similar reasons and others, claim 9, which depends from claim 7 and includes additional limitations, is believed to be patentable over Wilson et al. in view of Fischell et al. Thus, the rejection of claim 9 under 35 U.S.C. § 103(a) is improper and should be reversed.

5. Claim 9 is patentable over Wilson et al. in view of Fischell et al.

Claim 9 recites:

> 9. The method of claim 7, further comprising: viewing relative movement of a marker positioned on the flexible side sheath with respect to at least one marker positioned on the catheter, wherein the relative movement indicates that the distal end portion of the flexible side sheath is advancing into the ostium of the branch vessel, thereby indicating a relative position of the side opening of the main stent with respect to the ostium of the branch vessel.

Nothing in Wilson et al. or Fischell et al. appears to teach or suggest "viewing relative movement of a marker positioned on the flexible side sheath with respect to at least one marker positioned on the catheter, wherein the relative movement indicates that the distal end portion of the flexible side sheath is advancing into the ostium of the branch vessel, thereby indicating a relative position of the side opening of the main stent with respect to the ostium of the branch vessel", as recited in claim 9.

As discussed previously with respect to claim 1, Wilson et al. appears to merely teach providing a radiopaque marker on the guidewire lumen 55A of the main-vessel catheter 50 or providing a radiopaque marker on guidewire lumen 39A for a side-branch catheter 30. In either case, Wilson et al. appears to teach using a radiopaque marker on a single lumen of the

respective catheter to determine the proper orientation and alignment of the catheter with the side-branch vessel 5. In such a configuration, there would appear to be no relative movement between the marker(s). As such, nothing in the teachings of Wilson et al. appears to teach or suggest "viewing relative movement of a marker positioned on the flexible side sheath with respect to at least one marker positioned on the catheter, wherein the relative movement indicates that the distal end portion of the flexible side sheath is advancing into the ostium of the branch vessel, thereby indicating a relative position of the side opening of the main stent with respect to the ostium of the branch vessel", as recited in claim 9. Further, nothing in Fischell et al. appears to remedy this shortcoming of Wilson et al. Therefore, for at least these reasons, claim 9 is believed to be patentable over Wilson et al. in view of Fischell et al. Thus, the rejection of claim 9 under 35 U.S.C. § 103(a) is improper and should be reversed.

B. Conclusion

For the reasons stated above, the Examiner's rejections of claims 1-7, 9, and 24 under 35 U.S.C. § 103(a) should be overruled.

Respectfully submitted,

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J. Scot Wickhem, Reg. No. 41,376
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, Minnesota 55403-2420
Telephone: (612) 677-9050
Facsimile: (612) 359-9349
Scot.Wickem@cstlaw.com

IX. CLAIMS APPENDIX

1. A method of positioning a main stent in a main vessel at a vessel bifurcation such that a side opening in the main stent is positioned at an ostium of a branch vessel, the method comprising:

positioning a main guidewire in the main vessel such that a distal end of the main guidewire extends past the vessel bifurcation;

advancing a stent delivery system over the main guidewire to a position proximate the bifurcation, the stent delivery system comprising a catheter with a flexible side sheath attached thereto, wherein the catheter is received over the main guidewire, and wherein the main stent is positioned over the catheter with the flexible side sheath positioned to pass through an interior of the main stent and out the side opening in the main stent, the flexible side sheath having a distal end portion extending distal of the side opening of the stent;

subsequently, advancing a branch guidewire through the flexible side sheath attached to the catheter and into the branch vessel;

subsequently, advancing the catheter over the main guidewire while advancing the flexible side sheath over the branch guidewire, wherein the distal end portion of the flexible side sheath advances into the branch vessel; and

viewing relative movement of a marker positioned on the distal end portion of the flexible side sheath with respect to at least one marker positioned on the catheter when advancing the flexible side sheath over the branch guidewire, wherein the relative movement indicates that the distal end portion of the flexible side sheath is advancing into the ostium of the branch vessel, thereby indicating a relative position of the side opening of the main stent with respect to the ostium of the branch vessel.

2. The method of claim 1, wherein viewing the relative movement of the marker positioned on the flexible side sheath with respect to the at least one marker positioned on the catheter comprises: viewing an increasing separation distance between the marker positioned on the flexible side sheath with respect to the at least one marker positioned on the catheter as the catheter is advanced over the main guidewire while the flexible side sheath is simultaneously advanced over the branch guidewire.

3. The method of claim 1, wherein, viewing the at least one marker positioned on the catheter comprises viewing markers positioned adjacent the distal and proximal ends of the main stent.

4. The method of claim 1, further comprising: at least partially deploying the main stent within the main vessel.

5. The method of claim 4, further comprising: advancing a distal end of a second catheter over the branch guidewire and into the branch vessel.

6. The method of claim 5, further comprising: deploying a branch stent within the branch vessel, wherein the branch stent is positioned on the distal end of the second catheter.

7. A method of positioning a main stent at a vessel bifurcation between a main vessel and a branch vessel such that a side opening in the main stent is positioned at an ostium of the branch vessel, the method comprising:

positioning a main guidewire in the main vessel such that a distal end of the main guidewire extends past the bifurcation;

advancing a stent delivery system over the main guidewire to a position proximate the bifurcation, the stent delivery system comprising a catheter with a flexible side sheath attached thereto, wherein the catheter is received over the main guidewire, and wherein the main stent is positioned over the catheter with the flexible side sheath positioned to pass through the interior of the main stent and out the side opening in the main stent, the flexible side sheath having a distal end portion extending distal of the side opening of the stent;

subsequently, advancing a branch guidewire through the flexible side sheath and into the branch vessel; and

subsequently, advancing the catheter over the main guidewire while advancing the flexible side sheath over the branch guidewire, wherein the distal end portion of the flexible side

sheath advances into the branch vessel such that the side opening in the main stent is positioned at the ostium of the branch vessel.

9. The method of claim 7, further comprising: viewing relative movement of a marker positioned on the flexible side sheath with respect to at least one marker positioned on the catheter, wherein the relative movement indicates that the distal end portion of the flexible side sheath is advancing into the ostium of the branch vessel, thereby indicating a relative position of the side opening of the main stent with respect to the ostium of the branch vessel.

24. The method of claim 1, wherein at least partially deploying the main stent within the main vessel comprises inflating a balloon to expand the main stent into engagement with the main vessel.

X. EVIDENCE APPENDIX

None

XI. RELATED PROCEEDINGS APPENDIX

None